[bullet] rinse right away with water if it gets in eyes.''

(ii) The labeling states ''Stop use and ask a doctor [bullet] if skin irritation occurs or gets worse.''

(4) *For products containing benzoyl peroxide identified in § 333.310(a).*

(i) The labeling states ''Do not use if you [bullet] have very sensitive skin [bullet] are sensitive to benzoyl peroxide.''

(ii) The labeling states ''When using this product [bullet] avoid unnecessary sun exposure and use a sunscreen [bullet] avoid contact with the eyes, lips, and mouth [bullet] avoid contact with hair and dyed fabrics, which may be bleached by this product [bullet] skin irritation may occur, characterized by redness, burning, itching, peeling, or possibly swelling. Irritation may be reduced by using the product less frequently or in a lower concentration.''

(iii) The labeling states ''Stop use and ask a doctor if [bullet] irritation becomes severe.''

(d) *Directions.* The labeling of the product contains the following information under the heading ''Directions'':

(1) *For products applied containing any ingredient identified in § 333.310.* The labeling states ''[bullet] clean the skin thoroughly before applying this product [bullet] cover the entire affected area with a thin layer one to three times daily [bullet] because excessive drying of the skin may occur, start with one application daily, then gradually increase to two or three times daily if needed or as directed by a doctor [bullet] if bothersome dryness or peeling occurs, reduce application to once a day or every other day.''

(2) *For products applied and left on the skin containing benzoyl peroxide identified in § 333.310(a).*

(i) The labeling states the directions in paragraph (d)(1) of this section.

(ii) The labeling states ''[bullet] if going outside, apply sunscreen after using this product. If irritation or sensitivity develops, stop use of both products and ask a doctor.''

(3) *For products applied and removed from the skin containing any ingredient identified in § 333.310.* Products, such as soaps and masks, may be applied and removed and should include appropriate directions. All products containing benzoyl peroxide should include the directions in paragraph (d)(2)(ii) of this section.

(4) *Optional directions.* In addition to the required directions in paragraphs (d)(1) and (d)(2) of this section, the product may contain the following optional labeling: ''*Sensitivity Test for a New User.* Apply product sparingly to one or two small affected areas during the first 3 days. If no discomfort occurs, follow the directions stated (select one of the following: 'elsewhere on this label,' 'above,' or 'below').''

[56 FR 41019, Aug. 16, 1991, as amended at 75 FR 9776, Mar. 4, 2010]

PART 335—ANTIDIARRHEAL DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

Subpart A—General Provisions

Subpart B—Active Ingredients

Subpart C—Labeling

AUTHORITY: 21 U.S.C. 321, 351, 352, 353, 355, 360, 371.

SOURCE: 68 FR 18881, April 17, 2003, unless otherwise noted.

Subpart A—General Provisions

§ 335.1 Scope.

(a) An over-the-counter antidiarrheal drug product in a form suitable for oral administration is generally recognized as safe and effective and is not misbranded if it meets each condition in this part and each general condition established in § 330.1 of this chapter.

(b) References in this part to regulatory sections of the Code of Federal Regulations are to chapter I of title 21 unless otherwise noted.

§ 335.3 Definitions.

As used in this part:

(a) *Antidiarrheal.* A drug that can be shown by objective measurement to